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EXAMINER

D ABREU, MICHAEL JOSEPH

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/522,933	Applicant(s) TASS, PETER	
	Examiner Michael D'Abreu	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to communications filed on 21 October 2009. The Examiner acknowledges the amendments to claims 1 & 39-41 and addition of claims 42-45. Claim 1-45 are pending.

Claim Rejections - 35 USC § 101

2. Claims 42-45 are rejected under 35 U.S.C. 101, as being directed to non-statutory subject matter. The examiner notes independent claims 42 and 43 do not require implementation by a particular machine nor is the method transforming a particular article and accordingly does not pass the eligibility test for a statutory claim. An individual can perform the "detecting" and "monitoring" of brain activity manually, because the acquisition of any signal or use of equipment to perform these steps is not specified. Additionally, in claim 43, only the step of applying pulses is being claimed, not the monitoring of brain activity, and therefore can be performed by observing a pre-recorded EEG signal. The examiner notes that "desynchronizing" is simply modifying a neuronal rhythm and therefore the method cannot be classified as transforming a particular article. In order to overcome the 101 rejection, the examiner recommends amending the claim language to require implementation by a particular element or monitor.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 39-41 & 43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase “control means for generating with the stimulator a series of pulses within the determined frequency range” in Claim 39, and “generating...pulses having a frequency within the determined frequency range” in Claim 43, in combination with the other elements of the respective claims, is not supported by the disclosure. The examiner notes that the disclosure states that neuronal activity is monitored and the control unit determines the frequency range in which the neuronal activity develops an excitation; however, there is no mention of generating a series of pulses within that determined frequency range as claimed by the applicant and therefore is considered new matter since it was not originally presented. Paragraph 77 appears to discuss the frequency range, but indicates that the excitation stimulus or sequence is a phase determined from that frequency range and is not the same value as the frequency range measured by sensor 2. Accordingly, it is unclear as to how that same frequency range is claimed to be used by pulses stimulated by the second control means. The examiner suggests that the

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applicant employ the terminology used throughout the specification to properly claim the subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8, 10-19, 24-29, 33, 37-38, & 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (3780724).

7. Regarding Claims 1-6, 38, & 42 John discloses a device capable of testing a patient for neuronal rhythmic activity comprising of a control unit inherently evoking physiological brain activity (e.g. Column 3, lines 15-28; Claim 1). The device has several testing methods (e.g. Col 7-8), including one which generates a predictable periodic succession of pulses followed by another periodic succession of pulses (e.g. Col 9, lines 3-21) with or without a pre-determined rest or time delay (e.g. Col 8, lines 1-9). The examiner notes that the claims are comprising claims and accordingly are open ended and do not preclude additional pulses after the "single" pulse as recently amended. John specifies that the patient is stimulated visually and acoustically via a light or speaker as a stimulator (e.g. Col 3, lines 29-34). Means for detecting brain activity are further disclosed through scalp EEG electrodes (e.g. Col 3, lines 15-20), which are connected to the control unit by an amplifier (e.g. Col 3, lines 20-27). Furthermore, the

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device has feedback of patient reaction and connected to the control unit (e.g. Col 2, lines 21-47).

John's device generates a periodic succession of pulses for testing memory; however, it is not indicated that these pulses can control and abruptly desynchronize the phase dynamic of neuronal rhythmic activity. The examiner notes that short term memory itself is a neuronal activity and visual stimulations which are repeated to a patient create neuronal activity simply based on the rhythm of the stimuli. Furthermore, the applicant uses visual stimuli similar to John to control neuronal rhythmic activity. Therefore, it would have been obvious to one of ordinary skill to modify the device of John to direct the pulses towards neuronal rhythmic activity to yield the predictable results of providing stimuli which can control the phase dynamic of neuronal rhythmic activity.

8. Concerning Claims 7, 8, & 10, John's device carries out frequency scans (e.g. Col 4, lines 15-20), quantifies neuronal activity (e.g. Col 2, lines 23-30), and is designed to have the stimulator directly connected and activated by the control unit (e.g. Col 3, lines 62-67).

9. With respect to Claims 11-13, the apparatus as disclosed by John describes a T test computer, capable of investigating signals measured by the sensors through the use of the wavelet analysis (e.g. Col 4, lines 15-20). Furthermore, the device registers the change in the amplitude of the rhythm to be excited by recording that response (e.g. Col 4, lines 23-25).

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10. Claims 14 & 15, John's device has various testing methods including means for carrying out an entrainment (e.g. Col 7, lines 5-20) and desynchronization (e.g. Col 7, lines 44-50).

11. Regarding Claims 16-19, the T test computer in John's device is configured to test the quality of the entrainment (e.g. Col 4, lines 16-40) by determining the phase of the neuronal rhythms by matching the signals. The phase and amplitude of the neuronal activity is then evaluated (e.g. Col 4, 41-62).

12. With respect to Claims 24-27 and 33, John's device determines the vulnerable phase of the neural signal as defined by the applicant by varying the time spacing between the last excitation of the entrainment and the desynchronizing excitation signal (e.g. Col 8, lines 10-24). In one method, the device also changes the variation in time spacing for different values of intensity and in another method, increases the intensity in equidistant steps (e.g. Col 8, lines 18-22).

13. Regarding Claims 28 and 29, the prior art enables optimum stimulation parameters to be determined through the comparison of the results of multiple testing stimulations from where a minimization of the amplitude can be obtained (e.g. Cols 7-9).

14. Claim 37 is obviated by John's device as the stimulation is monitored by a program, in conjunction with a timer and switch (e.g. Col 3, 34-40).

15. Claims 9 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (3780724) in view of Nagano (5771443). John discloses the device substantially as claimed; however, specific means of quantifying neuronal activity or detecting stimulation parameters are not disclosed. The examiner notes that the

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applicant fails to disclose a clear or definitive advantage behind using the Hilbert transformation, matching a sine function, or integrating amplitude of power spectrum over frequency band over any other form of wavelet analysis. Nagano discloses the use of Hilbert transformation and other forms of wavelet analysis in the measurement and analysis of frequency deviation (e.g. Col 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by John, in view of the wavelet analysis of Nagano, to provide the predictable results of a more detailed examination of the neural activity.

16. In reference to Claim 23, John teaches the method as substantially as claimed. Although the amplitude response is analyzed by John's device in order to find marked differences between the responses (e.g. Col 7, lines 30-43), John does not plot the data as amplitude resetting curves in the analysis of neuronal activity. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to plot these data points in order to provide the predictable results of visually presenting the responses as figures rather than numbers. The applicant makes a graph of the amplitude data points - but the computer is still analyzing the data points in the same manner as the prior art. Plotting a set of data points on a graph to visually present a curve is common in basic experimentation and is not any sort of improvement.

17. Claims 20-22 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (3780724) in view of Czeisler (5545192). John discloses the device substantially as claimed. However, John's device does not employ the use of phase resetting curves in neural analysis. Czeisler uses phase resetting curves in the

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analysis of circadian rhythm. It would have been obvious to one of ordinary skill in the art to modify the method taught by John, to include phase resetting curves in order to provide the predictable results of projecting and analyzing the neural activity of the patient. Furthermore, John's device discloses the use of a T-test computer which is able to quantitatively analyze the response and phase dynamics of the desynchronizing neuronal activity both before and after stimulation (e.g. Cols 4-6).

Response to Arguments

18. Applicant's arguments filed 21 October 2009 have been fully considered but they are not persuasive.

19. Regarding support for Claim 39, the examiner cannot find in the disclosure, and the applicant has not referenced where the frequency range determined by the first means during the frequency scan, is the same as the frequency range of the entraining stimulus. Paragraph 77 appears to discuss the frequency range, but indicates that the excitation stimulus or sequence is a phase determined from that frequency range and is not the same value as the frequency range measured by sensor 2. Accordingly, it is unclear as to how that same frequency range is claimed to be used by pulses stimulated by the second control means. Additionally, applicant cites paragraph 83 as the support for the second control means, however, there is no mention of the determined frequency range or excitation - rather the paragraph is focused on amplitude and time spacing. The examiner suggests that the applicant employ the terminology used throughout the specification to properly claim the first and second control means.

20. In response to applicant's argument that none of the cited prior art documents teach a periodic succession of pulses that controls the phase dynamic of the neuronal rhythmic activity, the examiner notes that the terminology as defined throughout the specification of the application does not distinguish from the prior art. Although terms such as "phase dynamic", and "neuronal rhythmic activity" and "desynchronization" are not used throughout the prior art, John still is capable of treating a patient in the same manner as these terms are defined throughout the specification. Additionally, the fact

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that Applicant uses the visual stimulus for a different purpose does not alter the conclusion that its use in a prior art device would be prima facie obvious from the purpose disclosed in the reference and as expounded above.

21. Applicant's other arguments with respect to claims 39-41 have been considered but are moot in view of the new ground(s) of rejection, due to the amendments.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D'Abreu whose telephone number is (571)270-3816. The examiner can normally be reached on Monday - Friday, 0600 - 1630 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. D./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762